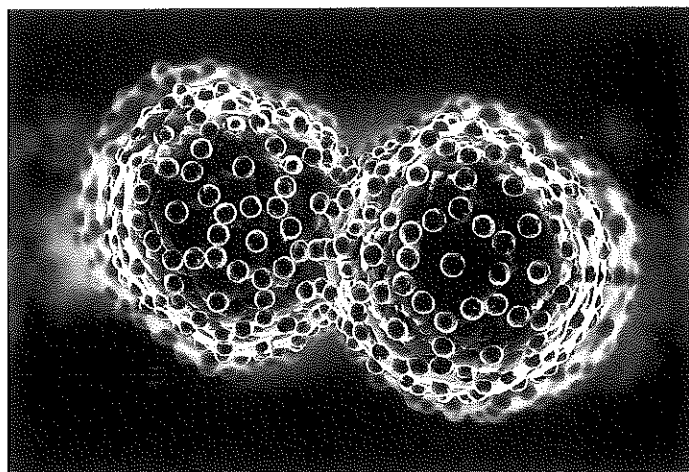


# Viral cancer therapy approved in the US

Modified herpes virus targets melanoma

The first virus therapy to target cancer has been approved in the US. Its main target will be melanoma, the most aggressive form of skin cancer. European approval is likely to follow before the end of the year, after the European Medicines Agency's advisory panel recommended it for approval in October.

Imlygic (talimogene laherparepvec, or T-Vec) is a genetically modified herpes simplex virus which targets melanoma lesions that cannot be removed completely by surgery. It is injected directly into the lesions, where it replicates inside cancer cells and produces an immune-boosting protein called GM-CSF (granulocyte-macrophage colony-stimulating factor). The cancer cells are eventually overwhelmed, rupture and die, releasing the new virus particles, the GM-CSF protein, and antigens derived from the tumour. Its developers say that together these may encourage the immune system to fight the tumour, but



T-Vec's limited treatment scope means it is unlikely to become a blockbuster

the exact mechanism of action is still under investigation.

In clinical trials, skin and lymph node lesions shrank in 16% of patients receiving Imlygic, with results persisting for at least six months; as compared to 2% in patients receiving recombinant GM-CSF (sargramostim). However, Imlygic does not improve overall survival, nor does it have any effect on melanoma that has

spread to the brain, bone, liver, lungs or other internal organs.

Imlygic is manufactured by BioVex, a US-based subsidiary of Amgen. The drug represents an important new option for patients with this aggressive and complex disease, says Sean Harper, executive vice-president of R&D at Amgen, who regards immunotherapy as 'an exciting area for cancer research'. Amgen anticipates the average cost of therapy

to be around \$65,000 (£43,000).

T-Vec is also being clinically tested in combination with other immunotherapy drugs. Amgen is collaborating with other companies, such as with Merck on studies to treat melanoma, and head and neck cancer, and with Roche to study the effect on breast and colon cancers.

With relatively small numbers of patients likely to benefit from the drug as it stands, Thomson Reuters Cortellis forecasts peak sales for Amgen of \$388 million by 2020. Eric Schmidt, senior research analyst in the healthcare sector at US firm Cowen and Company, believes that Imlygic is 'a very small drug' for Amgen, so modest, in fact, that his group has not calculated specific sales estimates. 'Its price is actually quite a bit lower than other first-in-class drugs and immunotherapies, which tend to be in excess of \$100,000,' he adds. *Maria Burke*

## Reference

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# Pharma kickback claims lead to individual prosecutions

Warner Chilcott and Novartis face fines for paying doctors

Two pharmaceutical powerhouses will have to pay hundreds of millions of dollars to address US government claims that they gave kickbacks to physicians across the country to induce them to prescribe their drugs. The charges led to the arrest of Warner Chilcott's ex-president, Carl Reichel, on 29 October.

Warner Chilcott US Sales, a subsidiary of the Ireland-based pharmaceutical manufacturer, pleaded guilty last month to a felony charge of healthcare fraud. The agreement was part of a global settlement with the US government in which Warner Chilcott agreed to pay \$125 million (£83 million) to

resolve its criminal and civil liability arising from alleged illegal marketing of several of its drugs.

Prior to Warner Chilcott's guilty plea and Reichel's arrest, two of the company's former district managers pleaded guilty to various charges, including conspiracy to commit healthcare fraud, and a third was criminally charged on a related matter.

'Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud,' stated Carmen Ortiz, the US attorney for Massachusetts.

Meanwhile, Swiss pharma firm Novartis has agreed in principle with the US Department of Justice (DoJ) to settle a kickbacks claim

for \$390 million, according to the company's latest quarterly financial report. The settlement has yet to be finalised, but the company is accused of inducing speciality pharmacies to boost prescriptions of its drugs by offering unlawful discounts and rebates in connection with Novartis's immunosuppressant drug Myfortic (mycophenolate sodium).

In April 2013, the DoJ filed a lawsuit against Novartis alleging that the company illegally paid pharmacies to get them to switch kidney transplant patients onto Myfortic.

Pharmaceutical companies have been paying out settlements such as these for more than 25 years, according to analysis by the consumer rights advocacy group Public Citizen. Sammy Almashat

with Public Citizen's health research group, says the Warner Chilcott case is the first one in which several top executives have pleaded guilty or are being charged. These individual prosecutions are needed to change the current state of affairs, according to Almashat. 'Right now, whatever fines that they may have to pay down the road pale in comparison to the profits that they can make by engaging in the criminal activity,' he says.

Analysis released by Public Citizen in September 2012 found that the \$30 billion in settlements paid out by pharmaceutical companies since 1991 represented just over two-thirds of the profits made by the 10 largest companies in 2010 alone. *Rebecca Trager*